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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/068,212	02/06/2002	Neal E. Fearnot	3433-338	8926

7590 09/19/2005

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EXAMINER

BARRETT, THOMAS C

ART UNIT PAPER NUMBER

3738

DATE MAILED: 09/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/068,212

Applicant(s)

FEARNOT ET AL.

Examiner

Thomas C. Barrett

Art Unit

3738

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 20 June 2005.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-45 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-45 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Response to Arguments***

Applicant's arguments with respect to claims 1-45 have been considered but are moot in view of the new ground(s) of rejection.

The Applicant argues: "In other terms, the proposed modification of using the Hiles et al. submucosa material in the Khosravi et al. stent devices would make the Khosravi et al. devices unsatisfactory for use as a stent. Therefore, there is no suggestion or motivation to combine the reference teachings and the cited references do not render the present inventive embodiments obvious." However, Khosravi et al. discloses, "As shown by FIG. 16, a sheet or membrane of material 160, which may be any material suitable for a vascular prosthesis or stent, is formed with protrusions or teeth 165 on both sides of the edges of the sheet." Hiles et al. teaches the use of a compliant submucosa material for a vascular prosthesis. Therefore the modified invention is satisfactory for its intended purpose, the motivation to combine provided in both Hiles et al as noted in prior office actions and in Khosravi et al.

Regarding the "attaching" limitation, the "extension" of Khosravi et al. is attached to the underlying material. The ratcheting attaches the extension to the underlying material as can be seen in the several cross-section drawings, e.g. Figs. 4, 16, 18, 20, 2, 28 and 29.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-45 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Khosravi et al. (5,618,299) as above in view of Hiles et al. (WO 98/25543). Khosravi et al. discloses a medical device (FIG. 26) comprising: a plurality of apertures (395) and extensions (390) shaped to be inserted into the apertures, thus attaching the extension to an underlying surface, and three layers comprising the two polymer layers as shown in FIG. 2, and an "intermediate" layer of pyrolytic carbon, a biomaterial (col. 3, line 56-col. 4, line 4). The extensions in the apertures as in FIG. 26 create non-continuous seams and a plurality of longitudinal seam edges. However, Khosravi et al. fails to disclose the device comprising a compliant collagenous material. Hiles et al. teaches a medical device comprising submucosa tissue (a compliant collagenous material) from porcine small intestine (p 4, lines 6-12), which is remodeled into host replacement tissue with site-specific structural and functional properties (p 3, lines 14-24). It would have been obvious to one of ordinary skill in the art to combine the teaching of a medical device comprising submucosa tissue (a collagenous material), as taught by Hiles et al., to a tubular medical device as per Khosravi et al., in order to provide a material that is remodeled into host replacement tissue with site-specific structural and functional properties.

***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Thomas C. Barrett whose telephone number is (571) 272-4746. The examiner can normally be reached Tuesday-Friday between 9:00 A.M. and 6:00 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4754. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to read 'Thomas Barrett', with a stylized flourish at the end.

Thomas Barrett  
Examiner  
Art Unit: 3738